CLAIMS

1. A device for promoting regeneration of an injured nerve comprising a nerve encasement structure and a plurality of biodegradable guiding means c h a r a c t e r i z e d in that at least a majority of the guiding means presents an in vivo degradation time t_1 being less than or approximately equal to a time t_c required for establishing regenerated contact between the ends of an injured nerve using the device for said regeneration.

2. A device according to claim 1, wherein the in vivo degradation time t_1 being less than the time t_c required for establishing regenerated contact between the ends of an injured nerve using the device for said regeneration.

3. A device according to any one of the preceding claims, wherein at least a major part of the nerve encasement structure presents an in vivo degradation time t_2 being longer than t_1 ($t_2 > t_1$).

4. A device for promoting regeneration of an injured nerve comprising a biodegradable nerve encasement structure, and a plurality of biodegradable guiding means, c h a r a c t e r i z e d in that at least a majority of the guiding means presents an in vivo degradation time t_1, at least a major part of the nerve encasement structure presents an in vivo degradation time t_2, and t_2 being longer than t_1 ($t_2 > t_1$).

5. A device according to any one of the preceding claims, wherein the plurality of biodegradable guiding means are a plurality of biodegradable guiding fibres.

6. A device according to any one of the preceding claims, wherein the material of the nerve encasement structure and the material of the guiding means each comprises one or more biodegradable polymers.

7. A device according to claim 6, wherein said one or more biodegradable polymers comprise(s) one or more biodegradable polyesters.

8. A device according to claim 7, wherein said one or more biodegradable polyesters comprise(s) PHB.

9. A device according to claim 7, wherein the material of the nerve encasement structure comprises PHB and the material of the guiding means comprises PHB.

10. A device according to claim 7, wherein the material of the nerve encasement structure comprises PHB and the material of the guiding means comprises PLGA.

11. A device according to any one of claims 6-10, wherein said one or more polymers comprised in the material of the guiding means present an average molecular weight which is lower than an average molecular weight of said one or more polymers comprised in the material of the nerve encasement structure.

12. A nerve regeneration device according to claim 11, wherein the material of the nerve encasement structure and the material of the guiding means each comprises PHB having an average molecular weight within the range of from 50 000 to 500 000.

13. A device according to claim 12, wherein the PHB average molecular weight of the nerve encasement structure is within the range of from 100 000 to 250 000 and

the PHB average molecular weight of the guiding means is within the range of from 50 000 to < 250 000.

14. A device according to any one of the preceding claims, wherein the nerve encasement structure comprises a compressed non-woven sheet of biodegradable fibres having an essentially unidirectional fibre orientation.

15. A device according to any one of the preceding claims, wherein the plurality of guiding means are biodegradable fibres in the form of a non-bonded fibre web having an essentially unidirectional fibre orientation.

16. A device according to any one of the preceding claims, further comprising a hydrogel matrix.

17. A device according to any one of the preceding claims, further comprising one or more biologically active substances or cells.

18. A device according to claim 17, wherein said one or more biologically active substances comprises a nerve growth promoting substance selected from the group consisting nerve growth factor (NGF); brain-derived neurotrophic factor (BDNF); neurotrophin-3 (NT-3); neurotrophin-4 (NT-4); glial growth factor (GGF); insulin-like growth factor (IGF); platelet-derived growth factor (PDGF); fibroblast growth factor (FGF); transforming growth factor (TGF); and epidermal growth factor (EGF).

19. A device according to claim 17, wherein said one or more biologically active cells is selected from the group consisting of endothelial cells; fibroblasts; Schwann cells; olfactory ensheathing cells; stem cells or precursor cells thereof.

20. A device according to any one of the preceding claims, wherein the guiding means occupies ≤ 2.0% by volume of the lumen formed by the nerve encasement structure.

21. A device according to any one of the preceding claims, wherein each guiding means of a majority of the guiding means has a cross-sectional dimension ≤ 50 μm.

22. A device according to claim 21, wherein each guiding means of a majority of the guiding means has a cross-sectional dimension ≤ 20 μm.

23. A device according to claim 22, wherein each guiding means of a majority of the guiding means has a cross-sectional dimension within the range of from 5 to 15 μm.

24. A kit for preparing a device for promoting regeneration of an injured nerve, said kit comprising a sheet and a plurality of biodegradable guiding means, c h a r a c t e r i z e d in that at least a majority of the guiding means presents an in vivo degradation time t_1 being less than or approximately equal to a time t_c required for establishing regenerated contact between the ends of an injured nerve using the device for said regeneration.

25. A kit according to claim 24, wherein the in vivo degradation time t_1 being less than the time t_c required for establishing regenerated contact between the ends of an injured nerve using the device for said regeneration.

26. A kit according to claim 24 or claim 25, wherein the sheet presents an in vivo degradation time t_2 being longer than t_1 ($t_2 > t_1$).

27. A kit for preparing a device for promoting regeneration of an injured nerve, said kit comprising a biodegradable sheet and a plurality of biodegradable guiding means, c h a r a c t e r i z e d in that at least a majority of the guiding means presents an in vivo degradation times t_1, at least a major part of the sheet presents an in vivo degradation time t_2, and t_2 being longer than t_1 ($t_2 > t_1$).

28. A kit according to any one of claims 24-27, wherein the plurality of biodegradable guiding means are a plurality of biodegradable guiding fibres.

29. A kit according to any one of claims 24-28, wherein the material of the sheet and the material of the guiding means each comprises one or more biodegradable polymers.

30. A kit according to claim 29, wherein said one or more biodegradable polymer comprises one or more biodegradable polyester.

31. A kit according to claim 30, wherein said one or more biodegradable polyester comprises PHB.

32. A kit according to claim 30, wherein the material of the sheet comprises PHB and the material of the guiding means comprises PHB.

33. A kit according to claim 30, wherein the material of the sheet comprises PHB and the material of the guiding means comprises PLGA.

34. A kit according to any one of claims 29-33, wherein said one or more polymers comprised in the material of the guiding means present an average molecular weight which is lower than an average molecular weight of

said one or more polymers comprised in the material of the sheet.

35. A kit according to claim 34, wherein the material of the and the material of the guiding means each comprises PHB having an average molecular weight within the range of from 50 000 to 500 000.

36. A kit according to claim 35, wherein the PHB molecular weight of the sheet is within the range of from 100 000 to 250 000 and the PHB molecular weight of the guiding means is within the range of from 50 000 to < 250 000.

37. A kit according to any one of claims 24-36, wherein the sheet comprises a compressed non-woven sheet of biodegradable fibres having an essentially unidirectional fibre orientation.

38. A kit according to any one of claims 24-37, wherein the plurality of guiding means are biodegradable fibres in the form of a non-bonded fibre web having an essentially unidirectional fibre orientation.

39. A kit according to any one of claims 24-38, further comprising a hydrogel material.

40. A kit according to claim 39, wherein the hydrogel is in a dehydrated state.

41. A kit according to any one of claims 24-40, further comprising one or more biologically active substances or cells.

42. A kit according to claim 41, wherein said one or more biologically active substance comprises a nerve growth promoting substance selected from the group con-

sisting of nerve growth factor (NGF); brain-derived neurotrophic factor (BDNF); neurotrophin-3 (NT-3); neurotrophin-4 (NT-4); glial growth factor (GGF); insulin-like growth factor (IGF); platelet-derived growth factor (PDGF); fibroblast growth factor (FGF); transforming growth factor (TGF); and epidermal growth factor (EGF).

43. A kit according to claim 41, wherein said one or more biologically active cells is selected from the group consisting of endothelial cells; fibroblasts; Schwann cells; olfactory ensheathing cells; stem cells or precursor cells thereof.

44. A biodegradable sheet for preparing a device for promoting regeneration of an injured nerve, c h a r a c t e r i z e d in having at least one surface at least partly coated with a dehydrated hydrogel material and a plurality of biodegradable guiding means, wherein at least a majority of the guiding means presents an in vivo degradation time t_1 being less than or approximately equal to a time t_c required for establishing regenerated contact between the ends of an injured nerve using device.

45. A biodegradable sheet for preparing a device for promoting regeneration of an injured nerve, c h a r a c t e r i z e d in having at least one surface at least partly coated with a dehydrated hydrogel material and a plurality of biodegradable guiding means, wherein at least a majority of the guiding means presents an in vivo degradation time t_1, at least a major part of the sheet presents an in vivo degradation time t_2, and t_2 being longer than t_1 ($t_2 > t_1$).

46. A biodegradable sheet according to claim 44 or claim 45, wherein the plurality of biodegradable guiding means are a plurality of biodegradable guiding fibres.

47. A biodegradable sheet according to any one of claims 44-46, said dehydrated hydrogel material further comprising one or more biologically active substances or cells.

48. Use of a plurality of biodegradable guiding means for promoting regeneration of an injured nerve, c h a r a c t e r i z e d in that at least a majority of the guiding means presents an in vivo degradation time t_1 being less than or approximately equal to a time t_c required for establishing regenerated contact between the ends of an injured nerve using the guiding means for said regeneration.

49. Use according to claim 48, wherein the plurality of biodegradable guiding means are a plurality of biodegradable guiding fibres.

50. Use according to claim 48 or claim 49, wherein the material of the guiding means comprises one or more biodegradable polymers.

51. Use according to claim 50, wherein said one or more biodegradable polymer comprises one or more biodegradable polyesters.

52. Use according to claim 51, wherein said one or more biodegradable polyesters comprises PHB.

53. Use according to claim 51, wherein said one or more biodegradable polyesters comprises PLGA.

54. Use according to claim 52, wherein PHB has an average molecular weight within the range of from 50 000 to 250 000.

55. Use according to any one of claims 48-54, wherein the guiding means are fibres in the form of a non-bonded fibre web having an essentially unidirectional fibre orientation.

56. A method for promoting regeneration of an injured nerve c h a r a c t e r i z e d in comprising the step of applying at said injured nerve a device according to any one of claims 1-23.

CLAIMS

1. A device for promoting regeneration of an injured nerve comprising a nerve encasement structure and a plurality of biodegradable guiding means c h a r a c t e r i z e d in that at least a majority of the guiding means presents an in vivo degradation time t_1 being less than a time t_c required for establishing regenerated contact between the ends of an injured nerve using the device for said regeneration.

2. A device according to claim 1, wherein at least a major part of the nerve encasement structure presents an in vivo degradation time t_2 being longer than t_1 ($t_2 > t_1$).

3. A device according to claim 2, wherein t_2 is longer than a time t_r required for the entire nerve regeneration process to be completed ($t_2 > t_r$).

4. A device for promoting regeneration of an injured nerve comprising a biodegradable nerve encasement structure, and a plurality of biodegradable guiding means, c h a r a c t e r i z e d in that at least a majority of the guiding means presents an in vivo degradation time t_1, at least a major part of the nerve encasement structure presents an in vivo degradation time t_2, t_2 being longer than t_1 ($t_2 > t_1$) and longer than a time t_r required for the entire nerve regeneration process to be completed ($t_2 > t_r$), and t_1 being less than t_r ($t_1 < t_r$).

5. A device according to claim 4, wherein t_1 is less than a time t_c required for establishing regenerated contact between the ends of an injured nerve using the device for said regeneration.

6. A device according to any one of the preceding claims, wherein the plurality of biodegradable guiding means are a plurality of biodegradable guiding fibres.

7. A device according to any one of the preceding claims, wherein the material of the nerve encasement structure and the material of the guiding means each comprises one or more biodegradable polymers.

8. A device according to claim 7, wherein said one or more biodegradable polymers comprise(s) one or more biodegradable polyesters.

9. A device according to claim 8, wherein said one or more biodegradable polyesters comprise(s) PHB.

10. A device according to claim 8, wherein the material of the nerve encasement structure comprises PHB and the material of the guiding means comprises PHB.

11. A device according to claim 8, wherein the material of the nerve encasement structure comprises PHB and the material of the guiding means comprises PLGA.

12. A device according to any one of claims 7-11, wherein said one or more polymers comprised in the material of the guiding means present an average molecular weight which is lower than an average molecular weight of said one or more polymers comprised in the material of the nerve encasement structure.

13. A nerve regeneration device according to claim 12, wherein the material of the nerve encasement structure and the material of the guiding means each comprises PHB having an average molecular weight within the range of from 50 000 to 500 000.

14. A device according to claim 13, wherein the PHB average molecular weight of the nerve encasement structure is within the range of from 100 000 to 250 000 and the PHB average molecular weight of the guiding means is within the range of from 50 000 to < 250 000.

15. A device according to any one of the preceding claims, wherein the nerve encasement structure comprises a compressed non-woven sheet of biodegradable fibres having an essentially unidirectional fibre orientation.

16. A device according to any one of the preceding claims, wherein the plurality of guiding means are biodegradable fibres in the form of a non-bonded fibre web having an essentially unidirectional fibre orientation.

17. A device according to any one of the preceding claims, further comprising a hydrogel matrix.

18. A device according to any one of the preceding claims, further comprising one or more biologically active substances or cells.

19. A device according to claim 18, wherein said one or more biologically active substances comprises a nerve growth promoting substance selected from the group consisting nerve growth factor (NGF); brain-derived neurotrophic factor (BDNF); neurotrophin-3 (NT-3); neurotrophin-4 (NT-4); glial growth factor (GGF); insulin-like growth factor (IGF); platelet-derived growth factor (PDGF); fibroblast growth factor (FGF); transforming growth factor (TGF); and epidermal growth factor (EGF).

20. A device according to claim 18, wherein said one or more biologically active cells is selected from the group consisting of endothelial cells; fibroblasts;

Schwann cells; olfactory ensheathing cells; stem cells or precursor cells thereof.

21. A device according to any one of the preceding claims, wherein the guiding means occupies ≤ 2.0% by volume of the lumen formed by the nerve encasement structure.

22. A device according to any one of the preceding claims, wherein each guiding means of a majority of the guiding means has a cross-sectional dimension ≤ 50 μm.

23. A device according to claim 22, wherein each guiding means of a majority of the guiding means has a cross-sectional dimension ≤ 20 μm.

24. A device according to claim 23, wherein each guiding means of a majority of the guiding means has a cross-sectional dimension within the range of from 5 to 15 μm.

25. A kit for preparing a device for promoting regeneration of an injured nerve, said kit comprising a sheet and a plurality of biodegradable guiding means, c h a r a c t e r i z e d in that at least a majority of the guiding means presents an in vivo degradation time t_1 being less than a time t_c required for establishing regenerated contact between the ends of an injured nerve using the device for said regeneration.

26. A kit according to claim 25, wherein the sheet presents an in vivo degradation time t_2 being longer than t_1 ($t_2 > t_1$).

27. A kit for preparing a device for promoting regeneration of an injured nerve, said kit comprising a biodegradable sheet and a plurality of biodegradable

guiding means, characterized in that at least a majority of the guiding means presents an in vivo degradation times t_1, at least a major part of the sheet presents an in vivo degradation time t_2, t_2 being longer than t_1 ($t_2 > t_1$) and longer than a time t_r required for the entire nerve regeneration process to be completed ($t_2 > t_r$), and t_1 being less than t_r ($t_1 < t_r$).

28. A kit according to any one of claims 25-27, wherein the plurality of biodegradable guiding means are a plurality of biodegradable guiding fibres.

29. A kit according to any one of claims 25-28, wherein the material of the sheet and the material of the guiding means each comprises one or more biodegradable polymers.

30. A kit according to claim 29, wherein said one or more biodegradable polymer comprises one or more biodegradable polyester.

31. A kit according to claim 30, wherein said one or more biodegradable polyester comprises PHB.

32. A kit according to claim 30, wherein the material of the sheet comprises PHB and the material of the guiding means comprises PHB.

33. A kit according to claim 30, wherein the material of the sheet comprises PHB and the material of the guiding means comprises PLGA.

34. A kit according to any one of claims 29-33, wherein said one or more polymers comprised in the material of the guiding means present an average molecular weight which is lower than an average molecular weight of

said one or more polymers comprised in the material of the sheet.

35. A kit according to claim 34, wherein the material of the and the material of the guiding means each comprises PHB having an average molecular weight within the range of from 50 000 to 500 000.

36. A kit according to claim 35, wherein the PHB molecular weight of the sheet is within the range of from 100 000 to 250 000 and the PHB molecular weight of the guiding means is within the range of from 50 000 to < 250 000.

37. A kit according to any one of claims 25-36, wherein the sheet comprises a compressed non-woven sheet of biodegradable fibres having an essentially unidirectional fibre orientation.

38. A kit according to any one of claims 25-37, wherein the plurality of guiding means are biodegradable fibres in the form of a non-bonded fibre web having an essentially unidirectional fibre orientation.

39. A kit according to any one of claims 25-38, further comprising a hydrogel material.

40. A kit according to claim 39, wherein the hydrogel is in a dehydrated state.

41. A kit according to any one of claims 25-40, further comprising one or more biologically active substances or cells.

42. A kit according to claim 41, wherein said one or more biologically active substance comprises a nerve growth promoting substance selected from the group con-

sisting of nerve growth factor (NGF); brain-derived neurotrophic factor (BDNF); neurotrophin-3 (NT-3); neurotrophin-4 (NT-4); glial growth factor (GGF); insulin-like growth factor (IGF); platelet-derived growth factor (PDGF); fibroblast growth factor (FGF); transforming growth factor (TGF); and epidermal growth factor (EGF).

43. A kit according to claim 41, wherein said one or more biologically active cells is selected from the group consisting of endothelial cells; fibroblasts; Schwann cells; olfactory ensheathing cells; stem cells or precursor cells thereof.

44. A biodegradable sheet for preparing a device for promoting regeneration of an injured nerve, c h a r a c t e r i z e d in having at least one surface at least partly coated with a dehydrated hydrogel material and a plurality of biodegradable guiding means, wherein at least a majority of the guiding means presents an in vivo degradation time t_1 being less than a time t_c required for establishing regenerated contact between the ends of an injured nerve using device.

45. A biodegradable sheet for preparing a device for promoting regeneration of an injured nerve, c h a r a c t e r i z e d in having at least one surface at least partly coated with a dehydrated hydrogel material and a plurality of biodegradable guiding means, wherein at least a majority of the guiding means presents an in vivo degradation time t_1, at least a major part of the sheet presents an in vivo degradation time t_2, t_2 being longer than t_1 ($t_2 > t_1$) and longer than a time t_r required for the entire nerve regeneration process to be completed ($t_2 > t_r$), and t_1 being less than t_r ($t_1 < t_r$).

46. A biodegradable sheet according to claim 44 or claim 45, wherein the plurality of biodegradable guiding means are a plurality of biodegradable guiding fibres.

47. A biodegradable sheet according to any one of claims 44-46, said dehydrated hydrogel material further comprising one or more biologically active substances or cells.

48. Use of a plurality of biodegradable guiding means for promoting regeneration of an injured nerve, c h a r a c t e r i z e d in that at least a majority of the guiding means presents an in vivo degradation time t_1 being less than a time t_c required for establishing regenerated contact between the ends of an injured nerve using the guiding means for said regeneration.

49. Use according to claim 48, wherein the plurality of biodegradable guiding means are a plurality of biodegradable guiding fibres.

50. Use according to claim 48 or claim 49, wherein the material of the guiding means comprises one or more biodegradable polymers.

51. Use according to claim 50, wherein said one or more biodegradable polymer comprises one or more biodegradable polyesters.

52. Use according to claim 51, wherein said one or more biodegradable polyesters comprises PHB.

53. Use according to claim 51, wherein said one or more biodegradable polyesters comprises PLGA.

54. Use according to claim 52, wherein PHB has an average molecular weight within the range of from 50 000 to 250 000.

55. Use according to any one of claims 48-54, wherein the guiding means are fibres in the form of a non-bonded fibre web having an essentially unidirectional fibre orientation.

56. A method for promoting regeneration of an injured nerve c h a r a c t e r i z e d in comprising the step of applying at said injured nerve a device according to any one of claims 1-24.